No. 23-1038

# In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION,

*Petitioner*,

v.

WAGES AND WHITE LION INVESTMENTS, L.L.C. D/B/A TRITON DISTRIBUTION, *ET AL.*,

*Respondents.*

On Petition for Writ of Certiorari to the United States Court of Appeals For the Fifth Circuit

## BRIEF OF VAPING INDUSTRY STAKEHOLDERS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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## INTERESTS OF *AMICI CURIAE*

*Amici* are small businesses and trade associations representing a diverse cross-section of the nation's flavored vaping product manufacturers, distributors, and retailers.[1] Millions of smokers have used flavored vaping products to quit smoking. Many of them had enough faith in the technology to start thousands of businesses to serve smokers. *Amici* thus share a common mission: advocating for reasonable regulations which maximize consumer access to less harmful flavored vaping products.

*Amici* have an interest here because the outcome will determine the future viability of flavored vaping products. The ruling will either force the U.S. Food and Drug Administration's (FDA) to recalibrate its policies concerning flavored products or decimate the vaping industry despite it having driven a significant reduction in smoking. The latter would ultimately harm public health.

## INTRODUCTION

The Court could plausibly believe this case arises because FDA either grossly miscalculated its expected receipt of vaping product Pre-Market Tobacco Product Applications (PMTA) or it consciously calculated the mass denial of millions of PMTAs.

FDA promulgated a rule in May 2016 to deem vaping products as subject to the Family Smoking Prevention and Tobacco Control Act (TCA), 123 STAT. 1776 (2009), codified as 21 U.S.C. § 387 *et seq*. FDA's

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[1] No counsel for any party authored this brief in whole or in part or made any monetary contribution, S. CT. R. 37.6, and notice of intent to file was provided to counsel for all parties more than 10 days in advance of the filing deadline, S. CT. R. 37.2. *Amici* are listed in the attached appendix.

fiscal analysis stated an expectation of receiving no more than 2,500 PMTAs,[2] later increased to 6,800 PMTAs.[3] Two months after the increase, however, FDA acknowledged receiving over 400 million vaping product registrations and predicted it would be unlikely to complete a timely review (within one year) if only a portion of those products filed PMTAs.[4]

More ominous, FDA represented the Deeming Rule would result in "significant product exit and reduced reentry,"[5] particularly for flavored products (predicting a 180-day market exit).[6] FDA could not have known this more than four years before receiving or reviewing any PMTAs absent a preordained plan to impose ban all flavored vaping products.

At the core of this case is FDA's erroneous presumption that all flavored vaping products carry the same youth risks. FDA applied this presumption despite knowing a stark distinction exists between the respective youth risks posed by "open-system" and "closed-system" vaping products: distinctions which concern the size of manufacturers; physical product characteristics; and their retail channels.

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[2] FDA, *Final Regulatory Impact Analysis Final Regulatory Flexibility Analysis Unfunded Mandates Reform Act Analysis*, Table 9 (May 2016). https://www.fda.gov/media/97875/download

[3] Decl. of Mitchell Zeller, *Am. Acad. I.,* (D. Md., No. 18-cv-883) filed Jun. 12, 2019, *ECF#120-1*.

[4] FDA, *Perspective: FDA's Preparations for the September 9 Submission Deadline* (Aug. 31, 2020).

[5] FDA, *Final Regulatory Impact Analysis*, at p. 20.

[6] *Id.*, at 152.

These distinctions also divine a difference in youths' product preferences. FDA knows youths overwhelmingly prefer flavored closed-system products and rarely choose their flavored open-system counterparts. This distinction is logical: closed-system products are smaller and more easily obtained and concealed than open-system products. FDA refused to tailor its PMTA standards to account for these risk distinctions *vis-a-vis* open-system flavored vapor products. FDA's miscalculations and refusal to regulate based upon its knowledge lie at the heart of this case.[7]

## SUMMARY OF THE ARGUMENT

The Court may scratch its head and wonder why a controversy exists about vaping products based upon the prior public statements of FDA's former leadership. In 2014, Mitch Zeller, the former Director of FDA's Center for Tobacco Products (CTP), opined in congressional testimony that it "would be good for public health" if adult smokers "completely switch all of their cigarettes" to vaping products.[8] In 2018, FDA's

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[7] The magnitude of FDA's failure is further accentuated by the fact that practically every trope uttered by anti-vaping advocates begins with the focus group-tested word "epidemic." Although FDA disclaims the propriety of such word, *see* American Vapor Manufacturers Ass'n, *The Future of Vaping in the US: A Conversation with FDA's Dr. Brian King*, Feb. 24, 2023 at 22:10 to 23:00, any issues of youth vaping substantially relates to the same closed-system products which its policies have allowed to proliferate the market.
https://www.youtube.com/watch?v=zfQ8u59z8Ac

[8] FDA, Statement of Mitchell Zeller, "*Progress and Challenges: The State of Tobacco Use and Regulation in the U.S.*" at 1:59:00, (May 14, 2014).

then-Commissioner concurred,[9] as does CTP's current Director.[10] They rooted their opinions in the TCA's preamble which evidences a clear congressional intent that FDA ensure adult smokers have access to lower risk products to help move them away from cigarettes. 21 U.S.C. § 387 *notes*.

The TCA requires that manufacturers file a PMTA to obtain FDA authorization for each vaping product. FDA must decide whether a product is "appropriate for the protection of the public health" (APPH) by evaluating all information and data included in each PMTA. 21 U.S.C. § 387j(c). This is not a one-size-fits-all process because the evidence warranting the authorization of one product may not justify the authorization of another.

For example, the APPH analysis requires FDA to consider how manufacturers propose to restrict youth marketing and access to their vaping products. The APPH analysis also requires that FDA balance any youth access concerns against all other evidence in the PMTA which warrants authorization. This was a clear congressional policy choice: the first ever *population-level* health standard which requires consideration of both a products' benefits and risks across the population as a whole. 21 U.S.C. § 387j(c)(4). This required that FDA account for all stakeholder interests by conducting a complete review of each PMTA.

FDA ignored the TCA's plain language when reviewing the Appellees' PMTAs and those of thousands of other vaping product manufacturers.

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[9] C-SPAN, *FDA Commissioner on E-Cigarettes and Public Health Concern*s, at 10:25, (Sept. 25, 2018).

[10] Perrone, M., *Insider Q&A: FDA official on vaping's "promise or peril,"* The Associated Press, (Sept. 26, 2022).

FDA, instead, applied an *ultra vires* one-size-fits-all approach which swung the PMTA review pendulum far to one side. The effect has been a *de facto* ban of all non-tobacco flavored (*e.g.*, mint and fruit) vaping products. *Wages & White Lion Inv. LLC v. FDA*, 90 F.4th 357, 384 n.5 (5th Cir. 2024) (*en banc*). FDA disproportionately skewed the APPH benefit/risk analysis by focusing on youth access at the expense of the benefits to adult smokers.

The above facts set the context for *amici's* following arguments.

*First*, FDA ignored Congress's clearly mandated process for adopting a tobacco product standard when implementing its *de facto* ban on flavored vaping products. The TCA prescribes how to adopt product standards (*i.e.* standards concerning a product's ingredients and constituents) by requiring that FDA engage in public notice-and-comment rulemaking. 21 U.S.C. § 387g(a). FDA, instead, imposed a *de facto* product standard through its PMTA adjudication process, relying upon *SEC v. Chenery Corp.*, 332 U.S. 194 (1947) *(Chenery II*), a case which countenanced agencies making *ad hoc* regulatory adjudications. The Court should overrule *Chenery II* as being incompatible with its current jurisprudence.

*Second*, the *amici* demonstrate why this case is perfectly suited for analysis under *Loper Bright Enterprises vs. Raimondo*, 603 U.S. ___, 144 S.Ct. 2244 (2024). *Amici* address elements of the APPH standard and how FDA arbitrarily ignored its requirements when considering the relevant factors as to the population as a whole by selectively focusing on distinct aspects of two particular "subpopulations." FDA erroneously and arbitrarily anchored its position as to the risks to one subpopulation by presuming that

all flavored vaping products are equally attractive to youths; ignoring that its presumption does not apply to open-system flavored products.

*Third*, FDA acted arbitrarily by: (1) articulating *post hoc* justifications; (2) failing to provide fair notice of its comparative efficacy standard; (3) changing a substantive position without displaying an awareness of, and explaining, the change; and (4) ignoring the Appellees' reliance interests. *Amici* discuss these elements in showing the *en banc* panel accurately concluded that FDA arbitrarily denied the Appellees' PMTAs.

*Finally*, the *amici* argue the TCA's deeming provision, 21 U.S.C. § 387a(b), is unconstitutional under the major question doctrine. *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120 (2000) held the regulation of tobacco products was a "major question" and FDA lacked regulatory authority absent specific enabling legislation. Congress identified four tobacco product subsets in the TCA for which it granted FDA immediate regulatory authority, 21 U.S.C. § 387a(b), but impermissibly delegated FDA with legislative authority to determine which additional tobacco products would be regulated. This was a determination which only Congress could make given *Brown & Williamson*. The Court should strike down 21 U.S.C. § 387a(b) as an unconstitutional legislative delegation.

## ARGUMENT

### I. FDA'S IMPOSITION OF A *DE FACTO* PRODUCT STANDARD THROUGH ITS PMTA ADJUDICATION PROCESS IMPERMISSIBLY IGNORED THE TCA'S RULEMAKING PROCESS.

This Court's ruling in *Loper, supra*. altered how courts review agency interpretations of ambiguous statutes. Congress requires that FDA base marketing decisions upon an ambiguous APPH standard for which it failed to articulate definitive metrics. FDA now argues that it does not have to articulate the APPH metrics. *See* FDA Brief 26, 27.

The TCA authorizes FDA to craft tobacco product standards which concern:

> "the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product."

21 U.S.C. §§ 387g(a)(4)(B), 387(*l*) defines flavorings as being an "additive." The TCA, however, cabins FDA's authority: mandating that it engages in notice-and-comment rulemaking for any proposed tobacco product standard. 21 U.S.C. § 387g(c)(2).

FDA ignored the TCA's clear and straightforward requirement; hastily creating an unannounced review standard for flavored products after the PMTA deadline, without an opportunity for manufacturers to supplement their PMTAs. FDA did so by requiring that manufacturers demonstrate their flavored products were more effective than a comparator tobacco-flavored product in causing smoking cessation. FDA, however, never identified either a comparator tobacco-flavored product or how many smokers must be

converted to achieve efficacy. FDA relies upon *Chenery II* to justify its application of a *de facto* tobacco product standard for flavored vaping products during the PMTA adjudication process in lieu of the notice-and-comment rulemaking process required by 21 U.S.C. § 387g.

FDA's pre-PMTA written guidance repeatedly stated its clear and unambiguous expectations. 90 F.4th at 363-68. Never did FDA ever mention before the PMTA deadline any intention to apply a comparative efficacy standard for flavored vaping products or the need for long-term studies to satisfy that standard. To the contrary, FDA specifically disclaimed the need for any specific type of studies, including long-term studies, let alone a comparative efficacy study. *Id*., at 363, citing FDA's October 2018 stakeholder presentation.

FDA then flipped the script after the PMTA deadline when adjudicating flavored open-system product PMTAs by adopting an *ad hoc* policy of requiring a showing they have a "magnitude of the potential benefit to adult smokers" which is "adequate to outweigh the risks to youth." Pet. App. 167a. This was the "surprise switcheroo" characterized by the Fifth Circuit's stay panel in *Wages & White Lion*, 16 F.4th 1130, 1138 (5th Cir. 2021), and the "wild goose chase" later characterized by the *en banc* panel, 90 F.4th at 362.

FDA believes this Court should countenance its PMTA review process, citing *Chenery II*, in arguing it owed no fair notice obligation to inform vaping product manufacturers of the "scientific goal line." FDA Brief 27. FDA justifies this position by arguing that Appellees and other industry stakeholders are "private part[ies]" who approach the government "to secure a

benefit to which [they] lack[] an established entitlement."[11] *Id*.

*Chenery II* concerned the propriety of an agency retroactively applying a new substantive legal standard during a regulatory adjudication process. The Court countenanced *ad hoc* agency regulatory adjudications by rationalizing that formal rulemaking is preferred but:

> "any rigid requirement to that effect would make the administrative process inflexible and incapable of dealing with many of the specialized problems which arise."

332 U.S. at 202. This Court expressed in *Chenery II* that agencies should be able to informally adjust their rulemaking processes as needed "to meet particular, unforeseeable situations" and "must be equipped to act either by general rule or by individual order." *Id*. This was meant to allow agencies the ability to respond quickly and efficiently to emergent situations, not adopt blanket policies which impact entire industries and are better left for formal rulemaking.

The continued adherence to *Chenery II* is inconsistent with basic notions of due process and fair notice; "empower[ing] agencies to issue retroactive regulations through adjudication" and "announce new rules during enforcement actions without any fair

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[11] FDA's argument is absolutely tone deaf since citizens routinely apply to the government to obtain some kind of benefit: like Social Security/Medicare benefits or veterans' benefits. They apply to agencies like EPA for a myriad of permits, or for more mundane things like drivers' licenses, business licenses and building permits. Does FDA seriously argue the government owes no obligation to be transparent about the rules for obtaining these benefits?

notice to the parties being regulated."[12] The late Justice Scalia observed that:

> "[r]udimentary justice requires that those subject to the law must have the means of knowing what it prescribes."[13]

FDA's serial application of its post-PMTA comparative efficacy standard is an illegitimate "subregulatory action."[14] *Chenery II* is also inconsistent with *Brown & Williamson's* holding in that an agency:

> "[r]egardless of how serious the problem [it] seeks to address," cannot "exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'"

529 U.S. at 125, citing *ETSI Pipeline Project v. Missouri,* 484 U.S. 495, 517 (1988). Congress set forth processes in the TCA which FDA must follow regarding the implementation of tobacco product standards.

FDA justified its actions by pointing to the "known risks to youth of marketing flavored [vaping products]."[15] Pet. App. 167a. Congress, however,

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[12] Donald F. McGahn, *Federalist Society National Lawyers Convention, Barbara K. Olson Memorial Lecture* (Nov. 17, 2017) at 29:20 – 29:31. https://fedsoc.org/conferences/2017-national-lawyers-convention#agenda-item-barbara-k-olson-memorial-lecture

[13] Antonin Scalia, *The Rule of Law as a Law of Rules*, The Univ. of Chicago L. Rev. 56:4 1175, 1179 (Fall 1989).

[14] McGahn at 24:14 - 24:22.

[15] FDA articulated the same justification *vis-à-vis* thousands of other flavored vaping product manufacturers.

specifically told FDA how to address this risk: adoption of a tobacco product standard through notice-and-comment rulemaking to regulate flavors as an "additive," 21 U.S.C. §§ 387g(a)(4)(B)(i) and 387(*l*).

FDA recently moved the goalposts again when adjudicating the PMTA for the NJOY® Ace menthol vaping product. It did so by announcing "the most stringent mitigation measures—specifically device access restrictions"—have the potential to mitigate against youth access to flavored vaping products.[16] FDA, however, has never adopted this position through the TCA's rulemaking process, instead applying *Chenery II* to make an end run around the TCA's statutory requirements.

FDA's view that it can adjust the PMTA review standard in real time as its experiences and understanding evolve is inconsistent with this Court's recent jurisprudence. Certainly, FDA can adjust its standards but only within the framework established by Congress.[17] FDA assumes its view is correct because other circuits have countenanced its *ad hoc* review process; seeking a continued adherence to *Chenery II*. FDA's position, however, is contrary to this Court's jurisprudence in *ETSI Pipeline*, *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142 (2012), *FCC v. Fox Television*, 556 U.S. 120 (2000) and *Brown & Williamson*.

Time has proven accurate Justice Jackson's dissent in *Chenery II* that ignoring the rulemaking

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[16] *Id.*, at 7.

[17] The Court should strictly construe FDA's adherence to the TCA's requirements given its pronouncement in *Brown & Williamson, supra.*, that the regulation of tobacco was constitutionally a major question.

process "would in practice, put most administrative orders above the law" by making judicial review "a hopeless formality for the litigant, even where granted to him by Congress" thus reducing "the judicial process in such cases to a mere feint." 332 U.S. at 210 (Jackson, J, dissenting). The Court should overrule *Chenery II* as being inconsistent with its current administrative law jurisprudence.

## II. THIS CASE WAS TAILOR-MADE FOR REVIEW UNDER THE NEW *LOPER* STANDARD.

*Loper, supra*., articulated a new standard for reviewing agency interpretations of ambiguous statutes. The TCA's APPH standard is requires that FDA's analysis had to consider "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product" upon:

> "(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
>
> (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products."

21 U.S.C. § 387j(c)(4). Congress did not express definitive baseline metrics for evaluating these two increased or decreased likelihoods when determining if a vaping product is APPH, but instead mandated that FDA balance the respective risks. *Id*.

FDA's application of the APPH standard evidences why this case is suited for review under *Loper*. FDA's Marketing Denial Order evidences its reliance upon

agency expertise;[18] something not conclusive but one of the factors having the "power to persuade," 144 S.Ct. at 2248, citing *Skidmore v. Swift & Co*., 323 U.S. 134, 140 (1944), "depend[ing] upon the thoroughness evident in [the agency's] consideration" and "the validity of its reasoning," *id.*, at 140. FDA, however, disregarded the panoply of relevant APPH factors by focusing upon two subfactors: the proven benefit in transitioning adult smokers away from cigarettes versus the risk of underage access and use. *See* Pet. App. 237a, *footnote vii* in which FDA acknowledged its failure to consider the respective benefits and risks of the Appellees' vaping products with respect to the population as a whole in lieu of the two identified subfactors.

FDA rationalized this approach by stating the "subpopulations" raised the "most significant public health concerns" which were "the most relevant in evaluating the impact on the population as a whole." *Id*. FDA thus concluded that Appellees' flavored vaping products failed to satisfy the APPH standard because the supporting evidence was "insufficient" to demonstrate they "would provide an added benefit that is adequate to outweigh the risks to youth." Pet. App. 228a. FDA's analysis was incomplete, however, because its APPH determination failed to account for the benefits or risks as to other population subsets *vis-à-vis* the adult smoker and youth subsets.

FDA further skewed its APPH analysis was further skewed because it by anchoring its youth risk determination upon a generalized finding that:

> "the availability of a broad range of flavors is one of the primary reasons for

[18] *See e.g.* Pet. App. 180a, 201a, 234a and 255a.

> the popularity of [vaping products] among youth."

Pet. App. 241a. FDA's assumption disregarded the fact that youths predominantly use flavored closed-system (pod or disposable) products and rarely use flavored open-system products like the Appellees manufacture. This explains why FDA failed to articulate that youths have historically used the Appellees' products. FDA's failure to accord these facts when crafting its review process *vis-à-vis* open system products ignored both reality and its own acknowledgment that PMTAs require individualized determinations.[19] FDA's fixation with youth risks led it to ignore two critical points: its prior representation about the importance of marketing plans and that science does not support its presumptions about flavored vaping products.

As to the former point, FDA's pre-PMTA representations stressed to Appellees the importance of manufacturers' marketing plans—they were intended to inform FDA how they proposed to keep their products away from youths. The fact that flavored open-system products are sold in age-restricted stores mitigates FDA's concern given its acknowledgment that youths typically neither use such products nor obtain them in that retail channel. FDA, however, never reviewed the Appellee' marketing plans "for the sake of efficiency" and justified that failure because the types of restrictions seen in previous PMTAs were insufficient to "decrease youth appeal to a degree significant enough to address

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[19] FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry* (June 2019), 86 FED. REG. 55,300, 55,414-32 (Oct. 5, 2021), codified as 21 C.F.R. § 1114.7 (listing of extensive information and data required for PMTAs).

and counter-balance the substantial concerns" about youth use.[20] Pet. App. 200a – 201a.

As to the latter point, the FDA stresses the role of flavored vaping products in youth initiation; pointing to data showing youths widely use non-tobacco flavored vaping products; and concluding the flavor of the products were the "primary reason" for use. Pet. App. 187a – 191a. FDA, however, articulated this presumption in the face of key scientific studies like a 2016 published systematic review which found 98 "conceptually different" potential onset risk predictors, including:

- age;
- lower socioeconomic status;
- poor academic performance;
- sensation-seeking or rebelliousness;
- future smoking intentions;
- receptivity to tobacco promotion;
- smoking susceptibility;
- smoking by family members and friends; and
- exposure to films,

whereas factors like higher self-esteem and high parental monitoring/supervision of the child appeared

[20] FDA noted the elements of NJOY's marketing as a basis for its marketing authorization but curiously told Petitioners those same elements were insufficient. *See* https://www.fda.gov/media/179499/download at 29.

to protect against smoking onset.[21] These risk factors, not a products' flavor, are drivers for tobacco initiation.

FDA also ignored the re-analyzed data[22] from a key study upon which it premised denying Appellees' products.[23] This re-analyzed data showed youth motivations for consuming flavored vaping products included various forms of harm reduction recognition:

- *they might be less harmful to me than cigarettes* (79.1%);
- *they might be less harmful to people around me than cigarettes* (78.1%);
- *they help people to quit smoking cigarettes* (59.5%).

The TCA mandates that FDA consider this data as a benefit to youths in its APPH analysis: a benefit which must fully or partially be viewed as offsetting its youth risk findings.[24]

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[21] Wellman RJ, *et al. Predictors of the Onset of Cigarette Smoking: A Systematic Review of Longitudinal Population-Based Studies in Youth*. AM. J. PREV. MED. 2016.

[22] Shiffman S., *et al., PATH Data: Harm Reduction is Teens' Top Reason for Using e-cigarettes*. Poster SRNT 2017, Pinney Associates.

[23] Ambrose BK, *et al. Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*. J. AM. MED. ASSOC. 2015.

[24] FDA's position is further undermined by the 2024 National Youth Tobacco Survey which revealed that 5.9% of youths vape at least once in a 30-day period and 1.55% vaped daily, the former representing a 70% reduction since 2019. *See* FDA News Release, *Youth E-Cigarette Use Drops to Lowest Level in a Decade* (Sept. 5, 2024).

FDA justifies its position by suggesting the names of the Appellees' products are youth appealing.[25] *See* FDA Brief 16. This position accentuates why carefully considering marketing plans was critical—it is far less significant that a particular flavored product is characterized as "child appealing" if they are only sold in age-restricted retail channels. The fact Appellees' flavored products, like other open-system products, are sold in such age-restricted stores is a relevant APPH factor which FDA ignored.

FDA also ignored a 2019 study on which it collaborated; a study finding that flavored products predominately help adult smokers. This study analyzed data from the 2013 through 2016 Population Assessment of Tobacco Health study, also collaborated on by FDA, in concluding that consistent and frequent product use over time, ***particularly with flavored E-Liquids***, is associated with higher adult smoking cessation rates.[26] 2012-2014 and 2017-2019 population studies, again underwritten by FDA, further showed a decrease in adults' preference for tobacco-, menthol- or mint-flavored vaping products over time; a stable preference for fruit-flavored products, but a significantly increased preference for chocolate/candy or other sweet-flavored products, and a slightly

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[25] FDA has never promulgated labeling/branding standards which restrict the use of product names or descriptors which could be youth-enticing.

[26] Glasser, A., *et. al., Patterns of E-cigarette Use and Subsequent Cigarette Smoking Cessation Over 2 Years (2013/2014–2015/2016) in the Population Assessment of Tobacco and Health Study*, NICOTINE & TOBACCO RESEARCH, 23:4, 669-677, Apr. 2021.

increased preference for other flavors.[27] The science reflected in these studies do not cease to exist simply because FDA fails to recognize them when crafting its APPH standards.

Peer reviewed scientific evidence of the adult preferences for flavored vaping products has only become more robust (to borrow from FDA's lexicon) since it denied marketing to the Appellees. For example, Gades, *et al*., an extensive literature review of 104 studies including clinical studies from 2007 to 2020, suggested that consumer access to a variety of non-tobacco flavors is likely to be associated with higher use levels and appeal for cigarette smokers, and that flavor variety "might facilitate complete substitution for cigarettes."[28]

The Gades study, however, warns policymakers that any:

> "[r]egulation of…flavors aimed at decreasing naïve uptake may inadvertently decrease uptake and complete switching among smokers, reducing the harm reduction potential of e-cigarettes."[29]

The Gades study frames the arguments here: "[e]vidence-based effects of regulating … flavors must be considered for the population as a whole, including

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[27] Du P, *et al.*, *Changes in Flavor Preference in a Cohort of Long-Term Electronic Cigarette Users*, ANN. AM. THORAC. SOC. 2020 May;17(5):573-581.

[28] Gades, Mari S., BA, *et al*., *The Role of Nicotine and Flavor in the Abuse Potential and Appeal of Electronic Cigarettes for Adult Current and Former Cigarette and Electronic Cigarette Users: A Systematic Review*, NICOTINE AND TOBACCO RESEARCH 2022:1332-1343, at 1332, 1339.

[29] *Id*. at 1332.

smokers."[30] FDA's *de facto* ban on flavored open system products is anything but "evidence-based."

Instead, FDA fixed its sights *vis-à-vis* flavored products and refused to budge despite science contradicting its position. FDA's fixed position with youth access to flavored vaping products has an unintended consequence which bears squarely upon the APPH standard. A 2023 Yale University School of Public Health study, **funded in part by FDA**, analyzed 5 years of cigarette sales data from 7 states and 375 localities that banned flavored vaping products in finding an increased use of 15 cigarettes (3/4 of a pack) for every banned 0.7ml flavored pod.[31]

This conclusion should have shaken FDA to its core and resulted in an immediate re-evaluation of how it viewed flavored vaping products, particularly open system products. FDA's concern with youths accessing

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[30] *Id.*; *see also*, *e.g.*, Robyn L. Landry, *et al., The role of flavors in vaping initiation and satisfaction among U.S. adults*, ADDICT. BEHAV. 2019 Dec;99:106077, at 14 (survey of over 1,000 adult vapors showing "[t]hose who used flavors, particularly mint/menthol and flavors other than tobacco flavor, had higher odds of reporting high satisfaction with vaping…than respondents who did not use flavored e-cigarettes."); Lin Li, Ph.D., *et al.*, *How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys*, NICOTINE AND TOBACCO RESEARCH 2021:1490-1497, at 1490-91, 1494 (survey of concurrent (or dual) users of cigarettes and vaping products finding that the greatest success in quitting occurred among adult smokers using sweet-flavored vaping products (13.8%) relative to tobacco-flavored ENDS (9.6%)).

[31] Friedman, A., *et al., E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales* (Sept. 26, 2023). *See* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4586701

tobacco products was the entire basis for its *de facto* ban on flavored vaping products. Yet, the Yale study suggests the occurrence of an unintended opposite effect—increasing cigarette sales among brands disproportionately used by youths.

FDA not only refused to recalibrate its focus in the face of the Yale study, it also authorized closed system vaping products sold in the retail channels it knows youths predominately prefer. The Yale study crystalized the ultimate issue here: "any public health benefits of reducing [vaping product] use via flavor restrictions may be offset by public health costs from increased cigarette sales."[32]

It was illogical for FDA to predicate its PMTA decisions upon youth access to flavored vaping products and then mass deny the products sold in the retail channels which do not admit youths while knowingly authorizing products sold in the channels that youths prefer. It is equally illogical for FDA to not consider as a mitigating factor that banning flavored vaping products carries an inherent risks of youths initiating or migrating to cigarettes.

*Loper* was critical to the review of agency determinations because it allows courts to look behind the curtain instead of reflexively acting as a rubber-stamp. FDA failed to stay true to the TCA's mandate to base marketing decisions upon the "population as a whole." Instead, FDA ignored critical differences between the two vaping product classes *vis-à-vis* risks to youths and then attempted to justify its desired policy goal by cherry-picking a select group of scientific studies. This is a prime example of an arbitrary agency action which *Loper* was meant to expose.

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[32] *Id.*

This Court noted in *Loper* that a "statute's meaning may well be that the agency is authorized to exercise a degree of discretion." 144 S.Ct. at 2262. Whatever discretion Congress granted FDA under the TCA did not include the authority to apply it in the way it has here. This case is tailor-made for review under *Loper* because FDA must now justify its many deviations from permissible regulatory practices and not expect automatic deference.

## III. THE *EN BANC* PANEL ACCURATELY FOUND THAT FDA'S PMTA REVIEW PROCESS FOR FLAVORED ENDS PRODUCTS WAS FRAUGHT WITH LEGAL DEFECTS.

FDA's PMTA review process for flavored vaping products suffers from four fatal defects: (1) a reliance upon *post hoc* justifications to justify the rejection of Appellees' PMTAs; (2) a failure to provide the Appellees fair notice when adopting its comparative efficacy standard; (3) a change of a substantive policy position without displaying an awareness of, or explaining, the change; and (4) a disregard of Appellees' reliance interests. Any of these flaws is alone sufficient to affirm the *en banc* panel.

### A. FDA'S *POST HOC* RATIONALIZATIONS; AN ATTEMPT TO JUSTIFY ITS FLAWED PMTA PROCESS.

The Appellees' arguments below fleshed out the significant legal flaws with FDA's standard for flavored vaping products. FDA responded with *post hoc* rationalizations which the *en banc* Fifth Circuit rejected on the basic proposition that the:

> "grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based."

90 F.4th at 371, citing *SEC v. Chenery Corp.,* 318 U.S. 80, 87 (1943). FDA's arguments below did not match the rationale underlying its marketing denial.

Over several years, FDA had many pre-PMTA interactions with manufacturers which affirmatively represented that PMTAs would not need the support of long-term studies, and certainly never informed them of the need for studies which compared the efficacy of their flavored vaping products to an unknown tobacco-flavored product. 90 F.4th at 372. Instead, FDA focused on the importance of the details of manufacturers' marketing plans, *id*., but its representations and assurances did not frame the scope of reviewing the Appellees' PMTAs.

The *en banc* panel noted that FDA predicated its marketing denial here on a determination that:

> "the *mere existence of flavor* was sufficient to justify denial of a PMTA because flavor standing alone was enough to prove that youth would use the proposed product and that youth use would outweigh any countervailing benefit to adults.

90 F.4th at 372. *See also* Pet. App. 200a – 201a n. xix. FDA's guidance, however, clearly articulated the critical importance of marketing plans in remediating against any youth-attractiveness of flavored vaping products.[33] Shockingly, FDA admitted "not even read[ing] the marketing plans." 90 F.4th at 372, citing Pet. App. 201a n. xix (acknowledging FDA's failure to review marketing plans).

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[33] FDA, Premarket Tobacco Product Applications and Recordkeeping Requirements, *supra.*, 84 FED. REG. 50,566, 50,581 (Sept. 25, 2019).

FDA defended this failure by pointing to an evolved mindset based on what it "learned" from "review[ing] PMTAs for flavored [products]."[34] Pet. App. 181a, n. vi. May an agency recalibrate policies as its knowledge and experience evolves? Sure, but not without limits. FDA could adopt a changed mindset as its experiences evolved. The law, however, required that FDA both acknowledge such evolution and articulate a "detailed justification" for it *before* abandoning existing expectations. *Encino Motorcars, LLC v. Navarro,* 579 U.S. ___, 136 S. Ct. 2117, 2125 (2016) (quotation omitted). Congress also added a public notice-and-comment rulemaking requirement. *See* 21 U.S.C. § 387g.

FDA tried to regulate on-the-fly because its erroneous PMTA expectations led to unrealistic compliance deadlines. FDA responded by extending the PMTA deadline outside the required rulemaking process, resulting in a federal court artificially setting an earlier PMTA date.[35] FDA realized the impossibility of complying with this artificial deadline,[36] and simply made up a new, after-the-fact evidentiary rule as a matter of expediency in order to dispatch with the deluge of PMTAs instead of seeking judicial relief from the artificial PMTA review deadline.

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[34] FDA employed this same explanation in its marketing decisions for all other flavored open-system vaping products adjudicated to date.

[35] The Maryland District Court in *Amer. Acad. of Pediatrics v. FDA*, 399 F. Supp.3d 479, 487 (D. Md. 2019) set a new May 9, 2020 PMTA deadline, later extended to September 9, 2020.

[36] *See* Reagan-Udall Foundation, *Operational Evaluation of Certain Components of FDA's Tobacco Programs*, 11 (Dec. 19, 2022).

FDA's hasty post-PMTA change of position was indeed the "surprise switcheroo" found by the Fifth Circuit stay panel, 16 F.4th at 1138, and embodied in the *en banc* panel's ruling. The latter panel did not err in refusing to defer to FDA arbitrarily springing a new and unexpected evidentiary requirement on Appellees after it was too late to comply.

A legitimate regulatory process should be able to stand the crucible of scrutiny without resort to *post hoc* rationalizations. FDA's *post hoc* rationalizations speak for themselves given its decision to double down before the *en banc* panel. *See* 90 F.4th at 373, 388. Those rationalizations are alone a sufficient basis to affirm the *en banc* Fifth Circuit.

### B. FDA'S ACTIONS VIOLATE THE FAIR NOTICE STANDARD.

The proposition that regulatory processes must be fair, open and transparent is a linchpin of this Court's jurisprudence. *Christopher*, *supra.*, at 156 (agencies must "provide regulated parties fair warning" of what it "prohibits or requires" before punishing noncompliance); *Fox Television*, *supra.*, at 515 (agencies cannot "depart from a prior policy *sub silentio* or simply disregard[ ] rules that are still on the books").

An agency cannot announce a particular position, create an "unfair surprise" by pivoting to a new position, and then penalize the reliance on such prior position, *Christopher* at 156-57, including regulation by informal guidance, *Morton v. Ruiz*, 415 U.S. 199, 235 (1974). The *en banc* Fifth Circuit laid bare that FDA's PMTA review process was anything but fair, open, and transparent.

FDA's August 2017 extension of the PMTA deadline commenced its interactions with vaping product stakeholders. 90 F.4th at 363. FDA undertook this step to buy time to clarify the APPH standard's mechanics and allow itself time to "promulgate [PMTA] instructions." *Id*. Next, FDA provided instructions on five occasions: October 2018 (stakeholder presentation); June 2019 (guidance document); September 2019 (proposed PMTA rule); October 2019 (public stakeholder meeting); and January 2020 (guidance document which prioritized its enforcement against non-tobacco and non-menthol flavored closed-system products). 90 F.4th at 363 – 366.

The *en banc* panel described its analysis of these FDA interactions with industry stakeholders as "dizzying" in observing that:

> "[n]ever in this long, winding, and byzantine regulatory process of meetings, PowerPoint decks, proposed rules, comment periods, guidance documents, and enforcement priorities did FDA *ever* say that it was contemplating an across-the-board ban on flavored products."

*Id*. at 368. FDA never gave "fair notice that *flavored* vaping product manufacturers had to submit robust scientific studies on *flavored*" open-system products. *Id*. at 368-9 (emphasis added).[37]

Instead, FDA honed its pre-PMTA focus on flavored closed-system products based upon specific characteristics which enhanced their youth appeal. 90

[37] In fact, FDA did not reflect its evolution of thought by contemporaneously rescinding its pre-PMTA guidance; a step which would have at least given stakeholders a hint of its changed expectations.

F.4th at 367-69, citing FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*: Guidance for Industry* (Apr. 2020) 5, 16, 17. FDA's Guidance positively contrasted open-system products because their characteristics lessened any youth appeal. 90 F.4th at 367, citing FDA Guidance 17.

FDA's Guidance and pre-PMTA industry dealings represented the fixing of an APPH standard to treat flavored open-system products *less strictly* than their closed-system counterparts. FDA did an about face regarding open-system flavored vaping products after the PMTA deadline without either notice to manufacturers or an opportunity to amend their PMTAs. The Fifth Circuit's characterizations of a "surprise switcheroo" and a "wild goose chase" were accurate and warranted.

The *en banc* panel's "dizzying" analysis evidences that FDA made a mockery of the fair notice principles. FDA took this mockery further by imposing its comparative efficacy standard without identifying a comparator tobacco-flavored product or defining how many smokers must quit for a flavored product to be "effective." It begs the question how manufacturers could conduct a reliable comparative efficacy analysis without knowing the above baseline metrics.

FDA saying one thing before the PMTA deadline but doing the opposite after the deadline is the hallmark of an arbitrary regulatory regime which lacks basic elements of fairness, openness, and transparency. FDA's failure to adhere to the fair notice standard is alone a sufficient basis to affirm the *en banc* Fifth Circuit.

### C. FDA Failed to Explain its Policy Switch Regarding Flavored E-Liquids.

Another linchpin of this Court's jurisprudence is the proposition that agencies cannot "depart from a prior policy *sub silentio*" or simply disregard existing rules and must "display awareness" of any policy change and support it with a "detailed justification" when the new policy alters "engendered serious reliance interests." *Fox Television*, *supra.*, at 515. It was unreasonable for FDA to embark on a departure from its pre-PMTA guidance and assurances without sufficiently explaining the change and giving accord to the Appellees' reliance interests.

FDA's numerous pre-PMTA actions evidence it was never prepared to receive and review PMTAs. For example, FDA announced plans in mid-2017 to issue "regulations outlining what information" it expected in PMTAs,[38] part of a larger policy shift which included a 4-year PMTA deadline extension.[39] FDA acknowledged in early 2018 that it had not "delineate[d] key requirements" of the PMTA process,[40] and by early 2019, still had not determined the PMTA "rules of the road."[41] FDA saw no urgency given the 2017 deadline

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[38] *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death* (Jul. 27, 2017), https://tinyurl.com/4e4xutd5.

[39] 82 FED. REG. 37,459, *et seq*. (Aug. 10, 2017).

[40] FDA, *Statement from FDA Comm'r Scott Gottlieb* (Mar. 14, 2018), https://tinyurl.com/22zuh3b4.

[41] *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2020: Hearings Before a Subcomm. of the H. Comm. on*

extension as it still expected receiving relatively few PMTAs.

FDA's numerous pre-PMTA representations disclaimed the need for manufacturers to submit specific studies, including long-term studies, only to pivot 180 degrees to a new position after the PMTA deadline. 90 F.4th at 363. FDA justified this pivot by saying its pre-PMTA guidance was merely "non-binding recommendations" and "never promised or committed itself" to doing any particular thing: a "wild goose chase."[42] 90 F.4th at 383.

Indeed, FDA's pre-PMTA assurances lulled the Appellees and thousands of other flavored open-system manufacturers to spend millions of dollars to timely file PMTAs. They did everything FDA asked in its pre-PMTA guidance, and remarkably did so in the face of both an arbitrarily shortened PMTA deadline and the many 2020 Covid business restrictions. FDA attempts to justify its radical position change by shrugging its shoulders and saying it was not bound by anything contained in its pre-PMTA industry dealings, a tact wholly inconsistent with *Fox Television, supra.* FDA's failure to sufficiently explain its policy shift regarding flavored open-system vaping products is alone a sufficient basis to affirm the *en banc* panel.

### D. FDA FAILED TO GIVE ACCORD TO APPELLEES' RELIANCE INTERESTS.

A final linchpin of this Court's jurisprudence is that agencies must accord reliance interests when considering a policy change. *See Christopher, supra.*, at 156-57 (agencies cannot penalize a party for a "good

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*Appropriations*, 116th CONG. 35 (2019) (statement of FDA Comm'r Gottlieb).

[42] William Shakespeare, Romeo and Juliet, act 2, sc. 4.

faith reliance" upon a prior position) and *Fox Television*, *supra.*, at 515 (agencies must take "serious reliance interests" into account). An agency must do so even when reversing a regulatory policy not enacted according to law. *Department of Homeland Security v. Regents of the University of California*, 591 U.S. 1 (2020).

FDA failed to accord the Appellees' reliance interests in its pre-PMTA assurances. 90 F4th at 384. FDA's policy change *vis-a-vis* open-system flavored vaping products was a significant policy shift given their substantial market space.[43] Aside from FDA's policy shift contradicting the TCA, it also failed to sufficiently accord the reliance interests of the Appellees and other flavored open-system product manufacturers. FDA's post-PMTA regulatory flip-flop was wholly inconsistent with this Court's reliance interests jurisprudence.

Here, FDA's pre-PMTA guidance could be interpreted to say that flavored vaping products needed to perform long-term scientific studies, but could also be reasonably interpreted to say that a manufacturer's flavored vaping product PMTAs did not need "specific studies," "[y]outh behavioral data," or "long-term studies." 90 F.4th at 385, citing FDA's October 2018 Guidance 18, 26. The former interpretation is weakened because "not a single sentence anywhere in the voluminous record" said that "manufacturers should submit long-term scientific studies on the differences between their new flavored

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[43] Kharrati, K., *Global E-Cigarette and Vape Market Size Likely to Surpass at a CAGR of 4.5% By 2033*, Custom Market Insights (Mar. 4, 2024). https://www.custommarketinsights.com/press-releases/e-cigarette-and-vape-market-size/

e-cigarette products and other nonflavored e-cigarette products." 90 F.4th at 385. Implicit in the *en banc* panel's ruling is the basic interpretative principle that any ambiguities in FDA's guidance documents were to be held against it. It correctly held that FDA could not send the Appellees ambiguous instructions and then penalize them for obeying the wrong one. *Id*.

The Appellees are in the same shoes as thousands of other open-system flavored product manufacturers who relied upon a reasonable interpretation of FDA's pre-PMTA assurances and representations. It would be one thing if the Appellees' interpretation and reasonable reliance occurred in isolation. It is a completely different thing when thousands of flavored vaping product manufacturers from all corners of the nation reached the same understanding. It is statistically improbable these manufacturers all reached the same conclusion by accident. The Court should hold FDA to its pre-PMTA representations.

## IV. THE TCA'S DEEMING PROVISION VIOLATES THE MAJOR QUESTIONS DOCTRINE.

The Court's recent jurisprudence evidences a significant reliance upon the separation of powers subset principle: the "major questions doctrine." It is implicated when an agency adopts a policy having a broad national effect without specific congressional authorization. *See e.g*., *West Virginia v. EPA*, 597 U.S. 697 (2022) (EPA lacked congressional authorization to regulate emissions from existing plants based on generation shifting mechanisms); *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758 (2021) (Centers for Disease Control's Covid-era eviction moratorium intruded into an area of vast economic and political significance without express Congressional authorization); and *Biden v. Nebraska*, 600 U.S. 477

(2023) (Department of Education's student loan debt cancellation plan lacked congressional authority).

*Brown & Williamson* is the foundation of this Court's recent major question doctrine jurisprudence. *Brown & Williamson* addressed the constitutionality of FDA invoking the Federal Food Drug and Cosmetic Act (FFDCA) to regulate tobacco products by classifying nicotine as a drug, and cigarettes as a drug delivery device. *See* 61 FED. REG. 44,619, *et. seq*. (Aug. 28, 1996). Congress had never authorized FDA's regulation of tobacco, instead constraining its regulatory efforts to labeling and advertising restrictions in response to the 1964 Surgeon General's report. 529 U.S. at 137-38. Congress considered 75 smoking-related bills between 1965 and 1978,[44] even proposing to amend the FFDCA to grant FDA regulatory authority.[45] Congress instead took a far lesser step by enacting the first federal cigarette labeling act.[46]

The foundation of the Court's major question holding in *Brown & Williamson* rested upon the proposition that tobacco products concerned a "significant portion of the American economy," and had a "unique place in American history and society" thus requiring congressional imprimatur. 529 U.S. at 159-60. Congress confirmed its understanding of this significance through its policy choice embodied in 15 U.S.C. § 1331 that the:

> "commerce and the national economy may be . . . protected to the maximum

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[44] Klebe, E.R., *Actions of the Congress and the Federal Government on Smoking and Health*, Congressional Research Serv., Report No. 79-219 (Sept. 26, 1979).

[45] *See* H.R. 2248, 89th Congress (1966).

[46] Klebe, *supra*.

> extent consistent with" the principle of consumers "being adequately informed about any adverse health effects."

*Id.* at 138-39.

*Brown & Williamson's* major question holding bound Congress and FDA concerning any future regulation of tobacco products. Congress, however, ignored this by using the TCA to impermissibly delegate seminal legislative authority to FDA. This is evident from Congress predicating the TCA's operative provisions upon the FFDCA's extant "tobacco product" definition which included:

> "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory...."[47]

21 U.S.C. § 321(rr)(1), but did not immediately subject all tobacco products to the TCA's requirements. 21 U.S.C. § 387a(b). Instead, Congress constrained FDA's authority to merely four specific product subsets (cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco), and specifically left all other tobacco products, including vaping products, outside the TCA's immediate scope. *Id.*

Congress' exclusion of vaping products is significant because it knew they existed.[48] Yet, Congress has never amended the TCA to expand the list of regulated products. Instead, it delegated plenary

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[47] The same definition applied at the PMTA deadline.

[48] *See e.g.* 155 CONG. REC. No. 50 at H3802 - H3805 (daily ed. Mar. 24, 2009) (statement by Rep. Buyer); 155 CONG. REC. No. 82 at S6009 - S6012 (daily ed. Jun. 3, 2009) (statement by Sen. Burr).

authority to the Health and Human Services Secretary to deem all other tobacco products through a regulatory deeming process. 21 U.S.C. § 387a(b). Congress disregarded *Brown & Williamson* by delegating to FDA the responsibility to identify any additional tobacco products to be regulated.

Congress compounded its impermissible delegation by not "provid[ing] standards for when and how [FDA] was to exercise its discretion to deem[.]" *Nicopure Labs, LLC v. FDA*, 266 F. Supp.3d 360, 392 (D. D.C. 2017). FDA admitted the lack of congressional standards ("Congress's choice of the deferential word 'deems' and the absence of any standard—beyond the requirement that the product meet the 'tobacco product' definition—demonstrate that Congress committed the exercise of this authority to the agency's broad discretion").[49] *Id*.

FDA exercised its deeming authority in May 2016 as to all other tobacco products, including vaping products, by way of is "Deeming Rule." 81 FED. REG. 28,974 (May 10, 2016).[50] FDA's claim of broad regulatory discretion begs the question given Congress's violation of *Brown & Williamson's* constraints. Therein, this Court dictated that Congress, and only Congress, could authorize FDA to regulate tobacco products. *Brown & Williamson* implicitly required that Congress specifically construct

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[49] The lack of guiding standards also presents a non-delegation doctrine question. *See Panama Refining Co. v. Ryan*, 293 U.S. 388, 430 (1935); *J.W. Hampton, Jr. & Co. v. U.S.*, 276 U.S. 394, 409 (1928).

[50] The validity of FDA's Deeming Rule fiscal analysis is presently being challenged under the Regulatory Flexibility Act, 5 U.S.C. §§ 601, *et seq*. *See Kealani Distrib, LLC v. FDA*, No. 22-cv-856 (E.D. Tx.).

the blueprint of the regulatory framework for tobacco products. This also implicitly required that Congress identify the specific tobacco products to be regulated as an integral part of crafting any regulatory framework. Congress's delegation of authority to FDA to make that identification of any additional products for purposes of 21 U.S.C. § 387a(b) violated the separation of powers doctrine. Independent of the *en banc* Fifth Circuit's analysis, the Court should rule the deeming provision in 21 U.S.C. §387a(b) is unconstitutional.

## CONCLUSION

Based on the foregoing, this Court should affirm the *en banc* Fifth Circuit's Opinion in its entirety.

October 8, 2024

Respectfully submitted,

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# APPENDIX

## APPENDIX
## LIST OF *AMICI CURIAE*

723VAPE, INC. (KY)

BREATHE EASY ALLIANCE OF ALABAMA

DERBECIGS LLC (KY)

DERBECIGS INDIANA LLC (IN)

FLORIDA SMOKE FREE ASSOCIATION, INC.

GEORGIA SMOKE FREE ASSOCIATION, INC.

KANSAS SMOKE FREE ASSOCIATION

KENTUCKY VAPING RETAILERS ASSOCIATION, INC. D/B/A KENTUCKY SMOKE FREE ASSOCIATION

IOWANS FOR ALTERNATIVES TO SMOKE AND TOBACCO, INC.

IOWA VAPE ASSOCIATION, INC.

J-VAPOR LLC, D/B/A NORTH SHORE VAPOR (MA)

LIQUID LABS LLC (NJ)

LOUISIANA VAPING ASSOCIATION, INC.

MARYLAND VAPOR ALLIANCE

MICHIGAN VAPE SHOP OWNERS, INC.

MIDWEST VAPE COALITION, INC.

MINNESOTA SMOKE FREE ALLIANCE

MISSISSIPPI VAPING ADVOCACY ASSOCIATION, INC.

MISSOURI SMOKE FREE, INC.

MONTANA SMOKE FREE ASSOCIATION, INC.

NEBRASKA VAPE VENDORS ASSOCIATION, INC.

NEVADA VAPING ASSOCIATION, INC.

NEW MEXICO SMOKE FREE ALLIANCE, INC.

NEW YORK STATE VAPOR ASSOCIATION, INC.

NORTH CAROLINA VAPING COUNCIL, INC.

OP MURSE HOLDINGS, LLC, D/B/A OPMH PROJECT (KY)
SOUTH CAROLINA VAPOR ASSOCIATION, INC.
VIRGINIA SMOKE FREE ASSOCIATION, INC.
WASHINGTON SMOKE FREE ASSOCIATION, INC.
WEST VIRGINIA SMOKE FREE ASSOCIATION, INC.
UNITED VAPERS ALLIANCE, INC.
VAPOR STOCKROOM, L.L.C. (KY)
VAPOR UNLIMITED, LLC (FL)